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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/795,860 | 07/12/2004 | Jeffrey Owen Phillips | 04242373 | 1266 |

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MAYER BROWN LLP
P.O. BOX 2828
CHICAGO, IL 60690

| EXAMINER | |
|---|---|
| CHOI, FRANK I | |
| ART UNIT | PAPER NUMBER |
| 1616 | |
| MAIL DATE | DELIVERY MODE |
| 04/01/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/795,860 | PHILLIPS, JEFFREY OWEN | |
| | Examiner | Art Unit | |
| | FRANK I. CHOI | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *75-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20071112,20060602,20050920,20050307*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice of Non-Compliant Amendment .

## DETAILED ACTION

### *Priority*

This application repeats a substantial portion of prior Application No. 10/407,552, filed 4/4/2003, and adds and claims additional disclosure not presented in the prior application (See below). Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

### *Drawings*

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 5 is handwritten. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### *Specification*

The amendment filed 6/11/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The range of "about 0.75 mEq (mmole) to about mEq(mmol) per 2 mg of omeprazole". The remarks do not indicate how the range was

determined and what specific disclosure in the original specification and/or claims support the amendment.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 75-92 are objected to because of the following informalities: The preliminary amendment (2/1/2008) lacks status modifiers. See 37 CFR 1.121. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claims 75-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 -82, 84-92 contain the limitation "at least 250 mg sodium bicarbonate". There is no support for this limitation as the disclosure cited by the Applicant does not set forth a range.

Claim 76 contains the limitation “about 56 to about 97 wt-%”. There is no support for this limitation as the disclosure cited by the Applicant does not set forth the same.

Claim 77 contains the limitation “about 1 to about 4 wt-%”. There is no support for this limitation as the disclosure cited by the Applicant does not set forth the same.

Claim 83 contains the limitation "about 250 to about 500 mg”. There is no support for this limitation as the disclosure cited by the Applicant does not set forth a range or an approximate amount.

Claim 88 contains the limitation "about 7 mEq to about 25 mEq". There is no support for this limitation in that the disclosure cited indicates that the range is "per 20 mg of omeprazole" and the Applicant has not shown that the range works within the requirements of claim 75 as to the amount of the PPI and amount of buffer including at least 250 mg of sodium bicarbonate.

Claim 90 contains the limitation "about 0.1 mEq to about 5 mEq per mg of proton pump inhibitor". There is no support for this limitation in that the disclosure cited was did not recite said range and the end point of 5 mEq was disclosed to be in relation to sodium bicarbonate per 2mg of omeprazole.

Claim 91 is dependent on cancelled claim 13.

Claim 91 contains the limitation "about 1 mEq to about 25 mEq". There is no support for this limitation as the disclosure cited by the Applicant does not set forth this range and the minimum of 1 mEq was disclosed in relation to 1 mEq per 2mg omeprazole.

Claim 92 contains the limitation "absorbed within about 10 to about 60 minutes". There is no support for this limitation in that the disclosure cited by Applicant refers to a solution not a tablet.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

With respect to the rejections below, since the Applicant has filed preliminary amendments containing new matter with respect to the Specification and claims, the Applicant is only entitled to the filing date of the present Application of March 8, 2004.

Claims 75-86, 88-92 are rejected under 35 U.S.C. 102(b) as being rejected by Phillip (US Pat. 6,489,346).

Phillip expressly discloses tablets as follows:

B. 10 mg Tablet Formula

| | |
|---|---|
| Omeprazole | 10 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount) |
| Calcium lactate | 175 mg |
| Calcium glycerophosphate | 175 mg |
| Sodium bicarbonate | 250 mg |
| Aspartame calcium (phenylalanine) | 0.5 mg |
| Colloidal silicon dioxide | 12 mg |
| Corn starch | 15 mg |
| Croscarmellose sodium | 12 mg |
| Dextrose | 10 mg |
| Peppermint | 3 mg |
| Maltodextrin | 3 mg |
| Mannitol | 3 mg |
| Pregelatinized starch | 3 mg |

C. 20 mg Tablet Formula

| | |
|---|---|
| Omeprazole | 20 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount) |
| Calcium lactate | 175 mg |
| Calcium glycerophosphate | 175 mg |
| Sodium bicarbonate | 250 mg |
| Aspartame calcium (phenylalanine) | 0.5 mg |
| Colloidal silicon dioxide | 12 mg |
| Corn starch | 15 mg |
| Croscarmellose sodium | 12 mg |
| Dextrose | 10 mg |
| Peppermint | 3 mg |
| Maltodextrin | 3 mg |
| Mannitol | 3 mg |
| Pregelatinized starch | 3 mg |

D. Tablet for Rapid Dissolution

| | |
|---|---|
| Omeprazole | 20 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount) |
| Calcium lactate | 175 mg |
| Calcium glycerophosphate | 175 mg |
| Sodium bicarbonate | 500 mg |
| Calcium hydroxide | 80 mg |
| Croscarmellose sodium | 12 mg |

Claims 75-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 584,588 in view Carroll, Kim et al. (US Pat. 5,703,097), Whittle et al. (US Pat. 6,268,385) and the acknowledged prior art.

EP 584,588 discloses a non-enteric coated anti-ulcer composition and a basic material and that the amount of basic material may be present in an amount of 50 to 2000 weights per 100 weight parts (Page 3, line 33). It is disclosed that the basic material is used to preserve the stability of the acid-labile imidazole derivative in the stomach (Page 6, lines 19-21). It is disclosed that omeprazole and imidazole are both acid-labile (Example 1 at pages 6,7).

Carroll et al. disclose the use of sodium bicarbonate to stabilize omeprazole in the gastric environment (Abstract).

Kim et al. discloses a method of treatment of treatment of gastric and duodenal ulcers and reducing acidity with 5-pyrrolyl-2-pyridylmethylsulfinylbenzimidazole derivatives which are dosed generally at 1 to 1000 mg/day, preferably 3 to 100 mg/day and also discloses comparative tests with omeprazole in the reduction of acidity (column 11, lines 20-31, Column 16, lines 45-68, Columns 17-20).

Whittle et al. discloses that esomeprazole is S-omeprazole (Column 19, lines 51-54). Methods of preparing oral dosage forms including mixing the active ingredient with an alkali material which creates a micro-pH of not less than pH of 7, preferably not less than a pH of 8 chosen from such materials as sodium, potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, or other suitable weak inorganic or organic acids; substances typically used in antacid preparations such as aluminum, calcium, and magnesium hydroxides; magnesium oxide or composite substances such as, for example, Al.sub.2 O.sub.3.6MgO CO.sub.2.12H.sub.2 O (Mg.sub.6 Al.sub.2.(OH).sub.16 CO.sub.3 4H.sub.2 O), MgO.Al.sub.2 O.sub.3, 2SiO.sub.2.nH.sub.2 O, wherein n is not necessarily a whole number and may be less than 2, or similar compounds (Column 43, lines 6-34). It is disclosed that the

above mixture may then be formulated into pellets or tablets or gelatin capsules which may then be used as cores for further processing, for example, enteric coating (column 43, column 44). It is disclosed that the tablets can contain lubricating agents, fillers and bulking agents and disintegrating agents (Columns 41, 42).

The Applicant acknowledges that omeprazole and lanzoprazole are H+, K+-ATPase proton pump inhibitors (Specification, Page 12).

The prior art disclose the combination of omeprazole and basic material. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose 10-40 mg of non-enteric coated benzimdazole PPI in combination with a buffer having at least 250 mg sodium biocarbonate and excipients containing disintegrant, lubricant and binder. However, the prior art amply suggests the same as the prior art discloses a non-enteric coated formulation containing basic material and omeprazole, that omeprazole is acid sensitive, the use of buffering agents such as sodium bicarbonate and magnesium hydroxide and tablets containing excipients such as disintegrants, lubricants, fillers and bulking agents. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the combination of the non-enteric coated PPI with the basic substance, such as sodium bicarbonate and magnesium hydroxide, would protect the PPI from stomach acid and that the product can be effectively administered as a tablet.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 75-92 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 162-196 of copending Application No. 10/407,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass tablets containing the combination non-enteric coated benzimadazole PPI, sodium bicarbonate and other buffers, including magnesium hydroxide, and binder, disintegrant and lubricant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 75-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-29 of U.S. Patent No. 6,7890,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because they

both encompass tablets containing the combination non-enteric coated benzimadazole PPI, sodium bicarbonate and other buffers, including magnesium hydroxide, and binder, disintegrant and lubricant.

***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
April 1, 2008

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616